HUMAN RESEARCH ETHICS APPROVAL

The University of Sydney confirms that this project meets the requirements of the National Statement on Ethical Conduct in Human Research.

Project identifier:	2023/HE000585
Project title:	Identifying the cellular pathophysiology of chronic trigeminal neuropathic pain
Application version:	1.02
Chief Investigator:	Professor Luke Henderson
Project team:	Professor Christopher Peck Miss Gaelle Emvalomenos Professor Kevin Keay Mr Lewis Crawford
Project start date:	10 Oct 2023
Project end date:	10 Oct 2027
Date of issue:	Tuesday, 20 August, 2024

Project summary

Chronic trigeminal neuropathic pain resulting from a nerve lesion/disease and affecting the mouth/face, is a highly prevalent condition having severe effects on an individual's quality of life. Although functional brain imaging studies have established brain regions involved in chronic pain processing, the altered engagement of neuroglia astrocytes and microglia remain under-investigated. To develop personalised pain treatments, a better understanding of these non-neuronal cells which encompass and support ascending and descending pain pathways needs to be established. The aim of this proposal is to use a multimodal approach to investigate underlying neurobiology of trigeminal neuropathic pain.

Summary of amendments

We have provided an updated action list surrounding SAE and SUSAE's, as well as appointed an independent physician to review periodically the data produced from this protocol. We have ascertained investigator brochures for both PET tracers, and these have been independently reviewed and deemed as safe for use by an independent medical physicist at the Royal Melbourne Hospital (Paul Einsiedel)

Documents approved

Document type	File name	Document version	Application version
Authorisation or approval	X24-0080 - New Correspondance.pdf	1	1.01
Other	X24-0080 - Original Correspondance.pdf	1	1.01
Participant Consent Form (PCF)	5b. Consent form v4 clean.docx	2	1.02
Recruitment or advertising material	Control Flyer V2.pptx	1	1.01

Survey or questionnaire	Day of Study Questionnaire.docx	1	1.01
Other	Lewis Crawford GCP Training awarded.png	1	1.01
Authorisation or approval	Ramachandran_PET Scan Study.pdf	1	1.02
Risk Assessment	2023_12_13 UoSyd MBC Research HREC_XXXX (1).pdf	1	1.01
Participant Information Statement (PIS)	4b. PIS Controls V4 clean.docx	2	1.02
Participant Information Statement (PIS)	3b. PIS Patients V4 clean.docx	2	1.02
Project description / Protocol	2. Protocol.docx	1	1.01
Recruitment or advertising material	PTN flyer V2.pptx	1	1.01
Other	Response Document 9th May 2024.pdf	1	1.01
Investigator Brochure (IB)	F-18_SMBT-1_Investigator_Brochure.docx	1	1.01
Investigator Brochure (IB)	F-18-FBR_Investigator_Brochure.docx	1	1.01

Conditions of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted on or before the anniversary of approval and a final report on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
    - Serious or unexpected adverse events (which should be reported within 72 hours).
    - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).
- Researchers working on this project must be sufficiently qualified by education, training, and experience for their role, or adequately supervised. Changes to the project team must be reported and approved.
- Researchers must disclose any actual, potential of perceived conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Research data and primary materials must be retained and stored in accordance with relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures, and governance requirements.
- If your research project is a clinical trial and is being sponsored by the University or is to be conducted on a University of Sydney site, you must comply with additional University governance requirements prior to commencing your Clinical Trial.
- The University may conduct audits on approved projects.

- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

Ethics Committee Representative

Chair
On behalf of the University of Sydney

The University of Sydney HRECs are constituted and operate in accordance with the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research (NHMRC). All personnel named on the project should be acquainted with these documents.

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